

Food and Drug Administration, HHS

§ 516.3

- 516.121 Meetings.
- 516.123 Informal conferences regarding agency administrative actions.
- 516.125 Investigational use of minor species new animal drugs to support indexing.
- 516.129 Content and format of a request for determination of eligibility for indexing.
- 516.131 Refuse to file a request for determination of eligibility for indexing.
- 516.133 Denying a request for determination of eligibility for indexing.
- 516.135 Granting a request for determination of eligibility for indexing.
- 516.137 Notification of decision regarding eligibility for indexing.
- 516.141 Qualified expert panels.
- 516.143 Written report.
- 516.145 Content and format of a request for addition to the index.
- 516.147 Refuse to file a request for addition to the index.
- 516.149 Denying a request for addition to the index.
- 516.151 Granting a request for addition to the index.
- 516.153 Notification of decision regarding index listing.
- 516.155 Labeling of indexed drugs.
- 516.157 Publication of the index and content of an index listing.
- 516.161 Modifications to indexed drugs.
- 516.163 Change in ownership of an index file.
- 516.165 Records and reports.
- 516.167 Removal from the index.
- 516.171 Confidentiality of data and information in an index file.

Subpart D [Reserved]

Subpart E—Conditionally Approved New Animal Drugs For Minor Use and Minor Species

- 516.1684 Paclitaxel.

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Subpart A—General Provisions

§ 516.1 Scope.

(a) This part implements section 573 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ccc-2) and contains the following subparts:

- (1) Subpart A—General Provisions.
- (2) Subpart B—Designation of a Minor Use or Minor Species New Animal Drug.
- (3) Subpart C [Reserved]
- (4) Subpart D [Reserved]
- (b) References in this part to regulatory sections of the Code of Federal

Regulations are to Chapter I of Title 21, unless otherwise noted.

§ 516.2 Purpose.

This part establishes standards and procedures for implementing section 573 of the act, including designation of minor use or minor species new animal drugs and associated exclusive marketing rights.

§ 516.3 Definitions.

(a) The definitions and interpretations contained in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to those terms when used in this part.

(b) The following definitions of terms apply to all subparts of part 516:

Active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule, responsible for the pharmacological action of the drug substance.

Functionally superior means that a drug has been shown to provide a significant therapeutic or physiologic advantage over that provided by a conditionally-approved or approved MUMS drug, that is otherwise the same drug, in one or more of the following ways:

- (i) The drug has been shown to be more effective, as assessed by effect on a clinically meaningful endpoint in adequate and well-controlled clinical trials, than a conditionally approved or approved MUMS drug, that is otherwise the same drug. Generally, this would represent the same kind of evidence needed to support a comparative effectiveness claim for two different drugs; in most cases, direct comparative clinical trials will be necessary; or
- (ii) The drug has been shown to be safer than a conditionally-approved or approved MUMS drug, that is otherwise the same drug, in a substantial portion of the target population, for example, by the elimination of an ingredient or contaminant that is associated with relatively frequent adverse effects. In some cases, direct comparative clinical trials will be necessary.